

REMARKS

After entry of the present amendments Claims 1-3, 8-27, 32, 34, and 35 will be pending. Support for new Claim 35 can be found throughout the claims and specification as originally filed, for example paragraphs [0073], [0074], [0098], [0107] of the specification as published. No new matter is added. Applicants submit that this application is in condition for allowance and such action is earnestly requested. Each of the Examiner's reasons for rejection is addressed below.

As an initial matter, Applicants submit that the Examiner has not shown how any of the primary references, Bhaskar, General Foods, and Schreiber Foods, teach all of the elements recited in the claims. Thus, the rejections should be withdrawn for this reason.

It is well settled that the Examiner "bears the initial burden of presenting a *prima facie* case of unpatentability..." *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007). Until the Examiner has established a *prima facie* case of obviousness, the Applicant need not present arguments or evidence of non-obviousness. To establish a *prima facie* case of obviousness, the Examiner must establish at least three elements. First, the prior art reference (or references when combined) must teach or suggest all of the claim limitations: "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 165 U.S.P.Q. 494, 496 (CCPA 1970); ("the need to demonstrate the presence of all claim limitations in the prior art was not obviated [by KSR]", *Abbott Labs. v. Sandoz, Inc.*, 2007 WL 1549498, *4 (N.D. Ill. May 24, 2007)); *see also* M.P.E.P. § 2143.03. Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986); *Pharmastem Therapeutics v. Viacell, Inc.*, 491 F.3d 1342, 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007); *see also* M.P.E.P. § 2143.02. And finally, the Examiner must articulate some reason to modify or combine the cited references that renders the claim obvious. Merely establishing that the claimed elements can be found in the prior art is not sufficient to establish a *prima facie* case of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007).

Claims 1-3, 8-27, 32, and 34 stand rejected under 35 U.S.C. § 103 as unpatentable over U.S. Patent Publication No. 2003-0096036 to Bhaskar et al. (hereinafter "Bhaskar"), EP 0435573 to General Foods (hereinafter "General Foods"), or WO 82/01806 to Schreiber Foods

(hereinafter “Schreiber Foods”) in view of U.S. Patent No. 4,202,907 to Poarch (hereinafter “Poarch”).

Applicants again note that the Examiner has only generally alleged that Bhaskar discloses *some* of the features of independent Claim 1. The Examiner has failed to particularly point out how Bhaskar discloses *each* of the features of the claims, and has not provided any citations to any relevant teachings in Bhaskar or any particular sections of Bhaskar.

The Examiner has also only generally asserted that General Foods discloses various features of the claims in citing to the entire document, especially column 7, lines 12-28, and Example I and II. The sections of General foods fail to disclose each element recited in the claims. The Examiner has not pointed out with particularity how or where General Foods teaches or suggests each element.

The Examiner has also asserted that Schreiber Foods discloses various features of the claims citing the entire document, especially page 12, lines 1-26; page 26, lines 26-31; and page 27, lines 8-18. The sections of Schreiber Foods cited by the Examiner fail to disclose each element recited in the claims.

The Examiner then found that “[t]he claims differ as the recitation that the cation exchange serves to replace calcium and magnesium with sodium or potassium.” Office Action at page 3. The Examiner further found that “[i]t would have been obvious to a person of ordinary skill in the art, at the time the invention was made, to use the cation exchange as taught by Poarch in that of Bhaskar et al. (US 2003/0096036), General Foods (EP 0435573), and Schreiber Foods (WO 82/01806) because the use of cation exchange to replace one ion with another in the milk protein art is conventional. Applicant is using known components and process steps to obtain no more than expected results.” *Id.*

Thus, it appears that the Examiner’s rejections rest on using the cation exchange of Poarch in each of the processes of Bhaskar, General Foods, and Schreiber Foods separately.

The Combination of Bhaskar and Poarch Fails to Render the Claims Obvious

The Examiner rejected the pending claims in view of the combination of Bhaskar and Poarch. Bhaskar discloses milk protein concentrate (MPC), milk protein isolate (MPI), and cheese products. Bhaskar discloses reconstituting calcium depleted milk to form substantially

nugget free cheese by standard cheddaring methods. See paragraph [0076]. Bhaskar describes preparing an MPC ingredient without the use of clotting enzymes and only uses rennet to produce curd in a cheese making process, not to produce a solution comprising para kappa-casein that can be subsequently concentrated. Declaration of Ganugapati Vijaya Bhaskar at paragraphs 5-6. Making cheese with the reconstituted MPC as disclosed in Bhaskar does not make obvious the process as claimed.

Bhaskar fails to teach all of the elements of the claims. For example, it is clear that Bhaskar forms a coagulum and thus does not maintain a solution after adding a clotting enzyme. Declaration of Ganugapati Vijaya Bhaskar at paragraphs 5-6. Bhaskar discloses the use of rennet *to form a coagulum* as part of the standard cheddar process. Paragraphs [0079] and [0104] ("All preparations developed a coagulum at 40 minutes after rennet was added"). Thus, Bhaskar fails to disclose "adding a food grade milk clotting enzyme under reaction conditions appropriate to convert said kappa-casein to para kappa-casein *while maintaining a solution*". The methods for manufacturing MPC also do not disclose this feature. See Figure 1. Applicants note that the Examiner did not specifically indicate how this feature is taught by Bhaskar in making the rejections.

Additionally, Bhaskar fails to disclose *concentrating* the solution after deactivating or removing the enzyme, as recited in Claim 1. There is no concentration step after the formation of curds and whey in the process of Bhaskar. The Examiner also did not point out where she believes this feature is disclosed in Bhaskar. The Examiner has also not shown that any of the features of the pending claims are inherently present in Bhaskar.

Moreover, there is no reason to modify Bhaskar to perform the steps recited in Claim 1. Substituting the cation exchange step of Poarch in the process of Bhaskar does not lead to the presently claimed process. Declaration of Ganugapati Vijaya Bhaskar at paragraph 5. Bhaskar describes preparing an MPC ingredient without the use of clotting enzymes and only uses rennet to produce curd in a cheese making process, not to produce a solution comprising para kappa-casein that can be subsequently concentrated. Declaration of Ganugapati Vijaya Bhaskar at paragraph 5. In view of the different process concerns for producing a meat additive versus a cheese type product, Applicants also submit that there is no reason to combine steps of the *meat* producing processes of Poarch with the process of Bhaskar.

Poarch fails to make up for the deficiencies of Bhaskar. Poarch is concerned with processing milk to add to meat products and is not concerned with making a dairy or cheese product, such as those disclosed in Bhaskar. The Examiner found Poarch to disclose adjusting the divalent ion content using cation exchange. The Examiner found that it would have been obvious to use the cation exchange step taught by Poarch in the process of Bhaskar. Applicants disagree because the cation exchange of Poarch, used to treat milk for use as an additive to meat products, fails to disclose the cation exchange as claimed. Declaration of Ganugapati Vijaya Bhaskar at paragraphs 5 and 10.

The cation exchange of Poarch is performed on a different starting material and the conditions for adding a food grade milk clotting enzyme are different. The cation exchange step of Poarch is used on milk. In contrast, Claim 1 recites adjusting the divalent ion content of a solution having a kappa-casein containing milk protein which is an ultrafiltration retentate. The recited conditions for adding a food grade milk clotting enzyme are also different from those disclosed in Poarch (see col. 4, lines 3-19). The cation exchange of Poarch is performed on a different starting material and the conditions for adding a food grade milk clotting enzyme are different. It is clear that the substitution of ions is important in Poarch and that the substitution is different as recited in the claims because it is performed on a different material with different conditions.

Further, the goal of Poarch is to modify the milk so that it can be used as a meat additive to modify the texture of sausage to form "brittle" gel instead of a normal gel. The cation exchange of Poarch is concerned with producing a material with significantly different materials (e.g. meats and meat additives) versus making cheese type products.

Thus, Applicants submit that the cation exchange of Poarch is not equivalent to the recited cation exchange step. Thus, Poarch fails to make up for these deficiencies or suggest a process as claimed in Claim 1.

Applicants also respectfully submit that there is no reason to use the cation exchange step of Poarch in the process of Bhaskar because Bhaskar already discloses a cation exchange step. Declaration of Ganugapati Vijaya Bhaskar at paragraph 5. The cation exchange step of Bhaskar was suitable for their applications. Accordingly there is no reason to substitute the cation

exchange step of Poarch, which is focused on producing meat and meat additives, for the cation exchange step of Bhaskar. Declaration of Ganugapati Vijaya Bhaskar at paragraph 5.

Further, replacing the cation exchange step of Bhaskar with that of Poarch would change the principal of operation of Bhaskar. The cation exchange affects the properties of the treated material. Thus, performing a different cation exchange step on the materials of Bhaskar, such as the cation exchange of Poarch, would be expected to change the properties of the treated material and the principle of operation of the process of Bhaskar. Such modifications and combinations are inappropriate. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

There is also no reasonable expectation of success in modifying the process of Bhaskar as suggested by the Examiner. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986); *Pharmastem Therapeutics v. Viacell, Inc.*, 491 F.3d 1342, 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007); *see also M.P.E.P. § 2143.02*. Bhaskar fails provide any teaching that would suggest to one of skill in the art that it would be possible to adjust the divalent ion content of said protein solution to a predetermined level such that no substantial gel is formed after subsequent treatment with a milk clotting enzyme. Further, since they are *trying* to coagulate to make cheese Bhaskar actually teaches away from this feature. Accordingly, the skilled artisan would have no reasonable expectation of success.

Applicants also submit that the ability to concentrate the material as claimed in Claim 1 is surprising because prior to the disclosure in the present application, a person of skill in the art would not believe that rennet casein was sufficiently soluble to allow formation of a renneted milk protein concentrate solution at neutral pH. Declaration of Ganugapati Vijaya Bhaskar at paragraphs 11-12. A person of skill in the art would have expected the material to form a gel. Thus, it was also surprising that the material could be dried or spray dried in the process as currently claimed in Claims 22 and 35. Declaration of Ganugapati Vijaya Bhaskar at paragraphs 11-12.

Accordingly, Applicants respectfully request withdrawal of the rejection because the combination does not teach all of the elements recited in the claims, the deficiencies of Bhaskar

are not made up for by Poarch, there is no reason to modify Bhaskar as suggested by the Examiner, and there is no reasonable expectation of success. In addition, even if a prima facie case was made, which it is not, it is rebutted by unexpected results.

The Combination of Schreiber Food and Poarch Fails to Render the Claims Obvious

The Examiner also rejected the pending claims in view of the combination of Schreiber Foods and Poarch. Schreiber Foods fails to disclose cation exchange as recited in Claim 1. Schreiber Foods discloses diafiltration and ultrafiltration, which removes both cations and anions. See page 16, line 24 to page 18, line 29. Schreiber Foods then discloses adjusting the ionic strength of the retentate using sodium chloride. See page 19, lines 9-26. Schreiber Foods fails to disclose cation exchange using a food grade cation exchanger as claimed in Claim 1. Poarch fails to make up for this deficiency. Also, as noted above, Poarch fails to disclose the cation exchange step as claimed.

Cation exchange is more than an obvious variation because there is no reason to use cation exchange in the process of Schreiber Foods. Such a step would be superfluous following the low pH ultrafiltration of Schreiber Foods, which depletes the product of calcium that could be exchanged for sodium or potassium. Declaration of Ganugapati Vijaya Bhaskar at paragraphs 8-9. Thus, the skilled artisan would have no reason to make the asserted combination.

Applicants also submit that there is no reason to combine Poarch with Schreiber Foods as suggested by the Examiner because Schreiber Foods already provides a different method of maintaining a solution (e.g. high ionic strength) after adding clotting enzyme. Declaration of Ganugapati Vijaya Bhaskar at paragraph 8. Thus, there is no reason to use the ion exchange of Poarch in the process of Schreiber Foods because the use of high ionic strength in Schreiber Foods was adequate to maintain a solution in the process of Schreiber Foods and, as mentioned above, addition of such a step would be superfluous. Declaration of Ganugapati Vijaya Bhaskar at paragraph 8.

Schreiber Foods also does not produce a concentrated milk protein solution as claimed. In contrast, Schreiber produces a gel that is a cheese or a cheese base. Declaration of Ganugapati Vijaya Bhaskar at paragraphs 8-9. The claimed process prevents coagulation by *changing* the

ion content of the protein solution using a food grade cation exchanger to replace calcium and magnesium with sodium or potassium. The recited process leads to greater reduction of calcium than is possible with ultrafiltration at milk pH as done in Schreiber, as much of the calcium in milk protein is tightly bound at milk pH. Declaration of Ganugapati Vijaya Bhaskar at paragraph 9. Applicants believe that the less effective calcium removal of Schreiber Foods results in gel formation of the treated material instead of the ability of the treated material to be concentrated and spray dried as recited in the claims. Regardless of the theory, the products of Schreiber Foods are gels that are a cheese or cheese base, not a concentrated milk protein solution (see page 15, lines 8-10; page 21, lines 5-8); Declaration of Ganugapati Vijaya Bhaskar at paragraph 9.

Further, there is no reason to combine Schreiber Foods and Poarch as suggested by the Examiner because Poarch is concerned about meat processing and is not concerned with making a dairy or cheese product, such as those disclosed in Schreiber Foods. Declaration of Ganugapati Vijaya Bhaskar at paragraphs 8-10. Thus, there is no reason to combine steps of the *meat* producing processes of Poarch with the processes of Schreiber Foods.

Further, replacing the use of high ionic strength to avoid coagulation of Schreiber Foods with the cation exchange of Poarch would change the principal of operation of Schreiber Foods. The use of the cation exchange of Poarch would replace higher ionic strength ions with lower strength ions thus decreasing the ionic strength of the processed solution described in Schreiber Foods. This modification would adversely affect the high ionic strength required in Schreiber Foods to avoid coagulation thereby changing the principal of operation of Schreiber Foods. Such modifications and combinations are inappropriate. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Applicants also submit that cation exchange was not routine in dairy processing at the time of the invention. At the time of the invention it was not known that it was possible to prepare a dried low lactose concentrated rennet casein product. Declaration of Ganugapati Vijaya Bhaskar at paragraphs 11-12. Further, the use of cation exchange requires superior results in order to justify the increased operation costs. The claimed process provides a different product that gives a superior, desirable result when drying.

Accordingly, Applicants respectfully request withdrawal of the obviousness rejections because the combination of Schreiber Foods and Parch fails to teach all of the elements of the claims and there is no reason to modify Schreiber Foods using the cation exchange of Parch as suggested by the Examiner.

The Combination of General Foods and Parch Fails to Render the Claims Obvious

The Examiner rejected the pending claims in view of the combination of General Foods and Parch. General Foods discloses ultrafiltration or diafiltration to lower the concentration of all minerals (e.g. both cations and anions) without any replacement. See whole document, in particular Examples I and II. General Foods only discloses *mechanical agitation* to avoid coagulation. ("it has been determined that the retentate can be maintained in a fluid state without formation of a coagulum during the fermentation step if the retentate is subjected to total movement during fermentation to prevent coagulum." Col. 7, ll. 17-22, emphasis added); Declaration of Ganugapati Vijaya Bhaskar at paragraph 7. There is no recognition in General Foods of any other way to avoid formation of a coagulum and no reason to replace one type of cation with another. Also, there is no reason to use another method to avoid formation of a coagulum because the mechanical agitation in General Foods is suitable for their application. Modifying General Foods to use a different method to prevent coagulation would change the principle of operation of General Foods. Such modifications and combinations are inappropriate. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

In contrast, the claimed process prevents coagulation by *changing* the ion content of the protein solution using a food grade cation exchanger to replace calcium and magnesium with sodium or potassium. The recited process leads to greater reduction of calcium than is possible with ultrafiltration at milk pH as much of the calcium in milk protein is tightly bound at milk pH. Thus, coagulation formation in the claimed processes is avoided by reducing the divalent ion content of the protein solution instead of the mechanical agitation of General Foods. Declaration of Ganugapati Vijaya Bhaskar at paragraph 7.

There is no reason to perform "cation exchange using a food grade cation exchanger to replace calcium and magnesium with sodium or potassium" in the process of General Foods. There is no reason in General Foods to replace one type of cation with another, and no recognition in General Foods of any other way to avoid formation of a coagulum than agitation, and no suggestion that another method would work.. Also, as noted above, such a modification would change the principle of operation of General Foods.

As noted above, Poarch fails to disclose the cation exchange step as claimed. Thus, Poarch fails to make up for the deficiencies of General Foods noted above. There is no reason to combine Poarch and General Foods because Poarch is concerned about meat processing and is not concerned with making a dairy or cheese product, such as those disclosed in General Foods. Thus, there is no reason to combine steps of the *meat* producing processes of Poarch with the processes of General Foods.

Applicants also submit that there is no reason to combine Poarch with General Foods as suggested by the Examiner. General Foods already provides a different method of maintaining a solution (mechanical agitation) after adding clotting enzyme. Thus, there is no reason to use the ion exchange of Poarch in the process of General Foods because the use of mechanical agitation in General Foods was adequate to maintain a solution in the process of General Foods.

Further, replacing the mechanical agitation or filtration steps of General Foods with the cation exchange of Poarch would change the principal of operation of General Foods. The use of the cation exchange of Poarch instead of the mechanical agitation or filtration steps of General Foods would modify the ions in the materials processed in General Foods thereby changing the properties of the materials. Such modifications and combinations are inappropriate. If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

Applicants also submit that cation exchange was not routine in dairy processing at the time of the invention. At the time of the invention it was not known that it was possible to prepare a dried low lactose concentrated rennet casein product. Declaration of Ganugapati Vijaya Bhaskar at paragraphs 11-12. Further, the use of cation exchange requires superior results in

order to justify the increased operation costs. The claimed process provides a different product that gives a superior, desirable result when drying.

Accordingly, Applicants respectfully request withdrawal of the obviousness rejections because the combination of General Foods and Poarch fails to teach all of the elements of the claims and there is no reason to modify General Foods using the cation exchange of Poarch as suggested by the Examiner.

In conclusion, Applicants submit that the Examiner has not shown how the primary references teach all of the elements recited in the claims, even if Poarch were considered to teach cation exchange. Also, as noted above, there is no reason to combine the primary references with Poarch, which is concerned with making meat. Further, modifying the primary references to use the cation exchange of Poarch, which is performed on milk, is inappropriate because it would change the mode of operation of the primary references. Accordingly, Applicants respectfully request withdrawal of the rejections of the pending claims.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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